DEC 1 8 2001

8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K013380.

Submitter:
ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:
October 5, 2001

Contact Person:
Edward Tung, Ph.D.

Product Names:
ACON® MOP One Step Opiate Test Strip
ACON® MOP One Step Opiate Test Device

Common Name:
Immunochromatographic test for the qualitative detection of Opiates in urine

Device Classification:
The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are similar to other FDA-cleared devices for the qualitative detection of Opiates in urine specimens. These tests are used to provide a preliminary analytical result (21 CFR 862.3650). These test systems have been classified as Class II devices with moderate complexity. Product code DJG has been assigned for these Opiate test systems.

Classification Name:
Opiate test system

Intended Use:
The ACON® MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are rapid chromatographic immunoassays for the qualitative detection of Opiates in urine at a cut-off concentration of 300 ng/mL for morphine. They are intended for the healthcare professional use.

Description:
The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Opiates in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Opiates in urine at a cut-off concentration of 300 ng/mL for morphine. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing Opiates at the concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Device:
Screener Opiate Test Drugscreen™ DIP Opiate Test
510(k) Number: K000273

Comparison to a Predicate Device:
A comparison of the features of the ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device versus the Screener Opiate Test Drugscreen™ DIP Opiate Test is shown below:

- Both tests are assays intended for the qualitative detection of Opiates in urine samples.
- Both tests are intended as a screening method that provides a preliminary analytical test result.
- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Opiates with a visual, qualitative end result.
- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off for morphine concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy:
A clinical evaluation was conducted using 300 clinical urine specimens including 10% of the samples with Opiate concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® MOP One Step Opiate Test Strip and Test Device with Screener Opiate Test Drugscreen™ DIP Opiate Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON MOP One Step Opiate Test Strip versus the Screener Opiate Test Drugscreen™ DIP Opiate Test:

Positive Agreement: 150 / 150 = 100% (98% - 100%*)
Negative Agreement: 150 / 150 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (98% - 100%*)

* 95% Confidence Intervals

ACON MOP One Step Opiate Test Device versus Screener Opiate Test Drugscreen™ DIP Opiate Test:

Positive Agreement: 150 / 150 = 100% (98% - 100%*)
Negative Agreement: 150 / 150 = 100% (98% - 100%*)
Overall Agreement: 300 / 300 = 100% (98% - 100%*)

* 95% Confidence Intervals

ACON MOP One Step Opiate Test Strip versus GC/MS at the cut-off of 300 ng/ml:

Positive Agreement: 141 / 141 = 100% (97% - 100%*)
Negative Agreement: 150 / 159 = 94% (89% - 97%*)
Overall Agreement: 291 / 300 = 97% (94% - 98%*)

* 95% confidence intervals

ACON MOP One Step Opiate Test Device versus GC/MS at the cut-off of 300 ng/ml:

Positive Agreement: 141 / 141 = 100% (97% - 100%*)
Negative Agreement: 150 / 159 = 94% (89% - 97%*)
Overall Agreement: 291 / 300 = 97% (94% - 98%*)

* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON MOP One Step Opiate Test Strip, ACON MOP One Step Opiate Test Device and Screener Opiate Test Drugscreen™ DIP Opiate Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Opiates at a concentration of 300 ng/mL. They are intended for healthcare professionals' use. The POL study demonstrated that these tests are also suitable for healthcare professionals at point-of-care site use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Director of Regulatory Affair
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

DEC 1 8 2001

Re: k013380
Trade/Device Name: ACON® MOP One Step Opiate Test Strip and ACON® MOP One Step Opiate Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: October 11, 2001
Received: October 12, 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K013380

Device Name: ACON® MOP One Step Opiate Test Strip

ACON® MOP One Step Opiate Test Device

Indications for Use: The ACON MOP One Step Opiate Test Strip and ACON MOP One Step Opiate Test Device are rapid chromatographic immunoassays for the qualitative detection of Opiate in human urine at a cut-off concentration of 300 ng/mL. They are intended for healthcare professional use.

Thomas C. Pastt for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013380

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or over-the-counter Use_____

(Per 21 CFR 801.109)